510(k) Summary
Fukuda Denshi model HG-500
Pulse Oximeter Module

12-20-01

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR part 807.92.

The assigned 510(k) number is: K013273

Submitter:

Fukuda Denshi, USA Inc.
17725 NE 65th St., Bldg C
Redmond, WA 98052
Tel: 425/881-7737
Fax: 425/869-2018

Contact Person:

Larry Walker
Regulatory Affairs Manager
Fukuda Denshi-Seattle Branch
17725 NE 65th St., Bldg C
Redmond, WA 98052
Tel: 425/881-7737
Fax: 425/869-2018

Date Prepared: September 19 , 2001

Device Name:

Proprietary Name:
Model HG-500 Pulse Oximeter Module

Common Name:
Pulse Oximeter

Classification Name:
Pulse Oximeter (§870.2700/74DQA)

Legally Marketed Device:

FUKUDA DENSHI model HG-302 Pulse Oximeter Module 510(k) number K945464. (The HG-500 is an addition to the DS-5300, 501(k) K964187)

Description:

The Fukuda Denshi model HG-500 Pulse Oximeter (SpO_2) module is designed for continuous, non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate when used as part of the DS-5300 Patient Monitoring System (K964187). The HG-500 is a module not a stand-alone device. As a module it will only operate when installed into a DS-5300 Patient Monitoring System. The Fukuda Denshi model HG-500 Pulse Oximetry module will function with all *Nellcor* reusable and disposable oximeter sensors.

The safety and efficacy of the HG-500 module has been established through various techniques. Review of the Fukuda Denshi model HG-302 predecessor product's history does not revel any complaints related to safety or effectiveness. There are no reports of adverse effects or reportable incidents for the HG-302 Pulse Oximeter product.

Statement of Intended Use:

The Fukuda Denshi model HG-500 Pulse Oximeter model is intended to be used for non-invasively continual monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate by trained medical professionals by or on the order of a physician. The model HG-500 monitor will function with all *Nellcor* reusable or disposible oximeter sensors.

The Fukuda Denshi model HG-500 Pulse Oximeter Module is intended to be used in all patient populations who are under the care of a physician, within the confines of a health care facility. The intended environment is critical monitoring situations where the Fukuda Denshi DS-5300 bedside patient monitor is being utilized with an IB-5006 Input Box.

The Fukuda Denshi HG-500 Pulse Oximeter module is NOT INTENDED FOR HOME USE.

The Fukuda Denshi HG-500 Pulse Oximeter module is intended to be used as a part of the Fukuda Denshi Ds-5000 series of bedside patient monitoring systems. The HG-500 will not function as a stand alone device.

Comparison to Predicate Device:

In summary, the HG-500 module is an improved version of the HG-302 Pulse Oximeter module, utilizing the latest technology, for use in the DS-5300 patient monitor.. Changes to the system include a reduction in size and weight to meet the requirements of the DS-5000 series modules. The HG-500 utilizes the *Nellcor* OEM MP-404 which is an upgrade of the *Nellcor* MP-203 used in the predicate. Each device continues to require the exclusive use of *Nellcor* manufactured sensors. Additionally the HG-500 allows increased motion filtering capability as compared to the predicate. The majority of the changes can be summarized as OEM circuit re-layout and a reduction in size

Technological Characteristics

The HG-500 Pulse Oximeter module, when used with the Fukuda Denshi DS-5000 series of patient monitor, (DS-5300, K964187) is designed to non-invasively measure functional oxygen saturation by calculating the light absorption of tissue, bone and blood during the pulsatile cycle. Inferred and red LED's are utilized as the light source. A photodiode senses the signal strength of the two wavelength of light which vary with the amount of light received through the tissue. The oximetry algorithm within the HG-500 processes the electrical information received from the sensor to provide real time SpO_2, Pulse Rate and Pulse Amplitude measurements.

The Pulse Oximetry circuitry is licensed, manufactured and purchased from *Nellcor Inc.* and is the same as used in the *Nellcor* N-395 Pulse Oximeter Model (K991823 and K993637) All algorithms are similar of those used in the used the Fukuda Denshi HG-302 Pulse Oximeter module (K945464) and are identical to those used in the *Nellcor* N-395.

In addition, the HG-500 possesses the identical motion filtering software that is resident in the *Nellcor* model N-395. This software reduces the the adverse effect of patient/ sensor motion, allowing the HG-500 to read through motion artifact. This allows the HG-500 to provide valid pulse rate and SpO_2 measurement during many types of patient motion situations.

Minor software changes were required to the DS-5300 Patient Monitoring system to accommodate the HG-500. Changes included adding additional

message indicators and assigning system priority SpO_2 function to the HG-500

TESTING

Laboratory testing was conducted to validate and verify that the Fukuda Denshi model HG-500 Pulse Oximeter module meet all design specifications and was substantially equivalent to the Fukuda Denshi model HG-302 Pulse Oximeter (K945464) and the *Nellcor* model N-395 Pulse Oximeter (K991823 and K993637). Additionally a non-invasive controlled hypoxia study was performed by *Nellcor Inc,* to validate the HG-500 compliance to sensor accuracy specification when when used with all eighteen models of *Nellcor* oxygen transducers.

Product tested included all environmental testing identified in the FDA's DCRND November 1993 "Reviewers Guidance Document for Premarket notification Submissions" Draft Guidance Document. Additional testing was performed to demonstrate compliance with the ANSI/AAMI standards ES1-1993, "Safe current limits for electro medical apparatus. Finally, testing was performed to verify that the design addressed all hazards and to validate the systems overall operation.

Although the device is neither life supporting nor life sustaining, diagnostic information derived from the use of the device and alarms generated by the device may be critical to the proper management of the patient.

The primary areas of risk for this device are the same as the predicate device and other devices in this class and are the following:

- Electrical shock
  Excessive electrical chassis leakage current can disrupt the normal electrophysiology of the heart and possibly leading to the onset of cardiac arrhythmias.
- Misdiagnosis
  - Inadequate design of the signal processing and measurement circuitry or programs can lead to generation of inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily.
  - Inadequate design of the device's software, used to make various measurements, can lead to generation of inaccurate diagnostic data. If inaccurate diagnostic data are used in

managing the patient, the physician may prescribe a course a course of treatment that places the patient at risk unnecessarily.

- Inadequate design of the systems ability to alert the users through audible and visual indicators, can lead to user mistrust and/or inadequate response to the patients condition. If an inadequate response to the patient's condition should occur the patient may unnecessarily be placed at risk.

The design of the HG-500 has taken into account all the above. The device is designed to meet UL 2601, CSA 22.2 and AAMI standards for electrical safety for medical equipment to prevent the possibility of excessive electrical leakage current to the patient.

Conclusion:

The conclusions drawn from the testing of the Fukuda Denshi model HG-500 Pulse Oximeter Model demonstrates the device is safe, as effective and performs as well or better than the legally marketed predicate device, the Fukuda Denshi model HG-302 Pulse Oximeter Module (K945464)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 0 2001

Mr. Larry Walker
Fukuda Denshi, USA Inc.
17725 NE 65th Street, Bldg. C
Redmond, WA 98052

Re: K013273
Fukuda Denshi Model HG-500 Pulse Oximeter Module
Regulation Number: 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II (two)
Product Code: DQA
Dated: September 24, 2001
Received: October 1, 2001

Dear Mr. Walker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

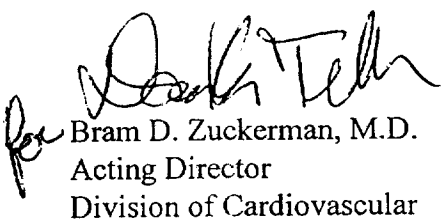
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



for Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use Statement

510(k) Number (if known): K013273

Device Name : Fukuda Denshi Model HG-500
Pulse Oximeter Module

Indications for use: The Fukuda Denshi model HG-500 Pulse Oximeter Module is indicated in those situations where it is desirable to perform continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin(SpO_2) and pulse rate for adult, pediatric and neonatal patients who are under the care of a physician, within the confines of a health care facility. It is not intended for home use

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDHR, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K013273

Prescription Use ✓ or Over the Counter Use_____
(Per 21 CFR 801.109